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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,530	05/09/2001	Kurt Klimpel	15280-290110	7146

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,530	KLIMPEL ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/15/2004 has been entered.

2. Claims 1-6,29-31 are under consideration.

3. The rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Leppla et al. (WO 94/18332) for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29,30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) There is no support in the specification as originally filed for the composition of claim 29. Regarding applicants comments about the cited passages in pages 9 and 20 of the specification, the aformentioned passages do not disclose the composition of claim 29.

b)There is no support in the specification as originally filed for the recitation of "herpes simplex virus protein" in claim 30. Regarding applicants comments about the cited passage in page 9 of the specification, the aformentioned passage, while disclosing use of the herpes simplex virus protein NS-5b does not disclose that other herpes simplex virus proteins can be used in the claimed invention.

There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed invention constitutes new matter).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-6,29,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leppla et al. (WO 94/18332) in view of Noteborn et al. (WO 95/03414).
Leppla et al. teach anthrax protective antigen (see last paragraph page 25 and first paragraph, page 26) and a fusion protein containing the PA binding domain of LF/toxin, wherein toxins are commonly full length proteins(see last paragraph page 25 and second paragraph, page 26). Leppla et al. teach that the fusion protein can contain the first 1-254 amino acids of LF (e.g. PA binding domain)(see pages 6 and 7). The name anthrax as used by Leppla et al. refers to Bacillus anthracis (see last paragraph page 3, continued on next page). Processed protective antigen is created when the anthrax protective antigen is administered in vivo. Leppla et al. teach that the toxin/fusion protein and PA are administered as a pharmaceutical composition (see page 27) containing saline (aqueous solution of physiologically compatible salts, see page 28). Leppla et al. do not teach the conjugate contains a viral protein. Noteborn et al. teach

the intracellular viral protein VP3 which can be used to kill tumor cells and other target cells (see page 8, third paragraph and page 2, last paragraph). Noteborn et al. teach immunoconjugates containing VP3 and a ligand that can be internalized by a cell (see page 9, third paragraph). The PA/PA binding domain of LF/toxin conjugate is internalized by a cell(see Leppala et al., page 4, last paragraph, continued on page 5). Leppala et al. teach the use of the aforementioned two component system to deliver a molecule into a cell (see claim 19 and 20). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Leppla teach the claimed invention except for use of a viral protein whilst Noteborn et al. teach immunoconjugates containing the viral toxin VP3 and a ligand that can be internalized by a cell and Leppla et al. teach the use of the aforementioned two component system to deliver a molecule into a cell. The recitation of an intended use in this product claim carries no patentable weight because the claimed product is the same as the product rendered obvious in the instant rejection. The dosage recited in the claims (as per defined in page 20, penultimate paragraph of the specification) is encompassed by the dose range disclosed in page 27, lines 24-25 of Leppla et al. While Leppla et al. do not teach the molar ratio recited in claim 31, Leppla et al. teach that the amount of PA and LF/fusion protein will be optimized using routine procedures. One of ordinary skill in the art would have been motivated to do the aformentioned because Leppala et al. teach the use of the aforementioned two component system to deliver a molecule into a cell and Noteborn et al. teach immunoconjugates containing VP3 and a ligand that can be internalized by a cell.

Regarding applicants comments that Leppala et al. do not disclose use of a viral protein in their conjugate, this issue is addressed by the addition of the Noteborn et al. (WO 95/03414) reference. Regarding applicants comments about dosage, the specification discloses on page 20 that:
For each recipient, the total vaccine amount necessary can be deduced from protocols for immunization with other vaccines. The exact amount of such antigen- APABP and PA compositions required will vary from subject to subject, depending on the species, age, weight and general condition of the subject, the particular fusion protein used, its

mode of administration, and the like. Generally, dosage will approximate that which is typical for the administration of other vaccines, and will preferably be in the range of about 10 ng/kg to 1 mg/kg.

Thus, regarding the functional dosage recited in the claims, said dosage will vary according to the antigen and particular parameters as per stated above. Said passage also discloses a general range of antigen to be used. Leppla et al., disclose administration of the instant invention at a dosage that overlaps that encompassed by the limitation now recited in the claims (see page 27, lines 24-25).
The recitation of an intended use carries no patentable weight in the instant product claims. Furthermore, the claimed composition as disclosed in Leppala et al. could induce a CTL response depending on the recipient and the protein used. For example, virtually any protein would be immunogenic/induce CTL if administered into another species (eg. the art recognizes that mouse Ig is immunogenic when administered to humans, etc). The invention rendered obvious in the instant rejection has the same structure as the claimed invention and would therefore have the same properties as the claimed invention. Regarding applicants comments that the viral protein recited in the claims would not kill the target, there is no limitation in the claims that the protein is not toxic to the cell. The CAV proteins disclosed by Noteborn are both cytotoxic and immunogenic (see claim 1). One of ordinary skill in the art would have been motivated to do the aformentioned because Leppala et al. teach the use of the aforementioned two component system to deliver a molecule into a cell and Noteborn et al. teach immunoconjugates containing VP3 and a ligand that can be internalized by a cell.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-2720841. The fax phone number for the organization where this application or proceeding is assigned is 703-

872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644